

•• CARBOGEN AMCIS EXPANDS CAPACITY FOR PARENTERAL DRUG MANUFACTURING

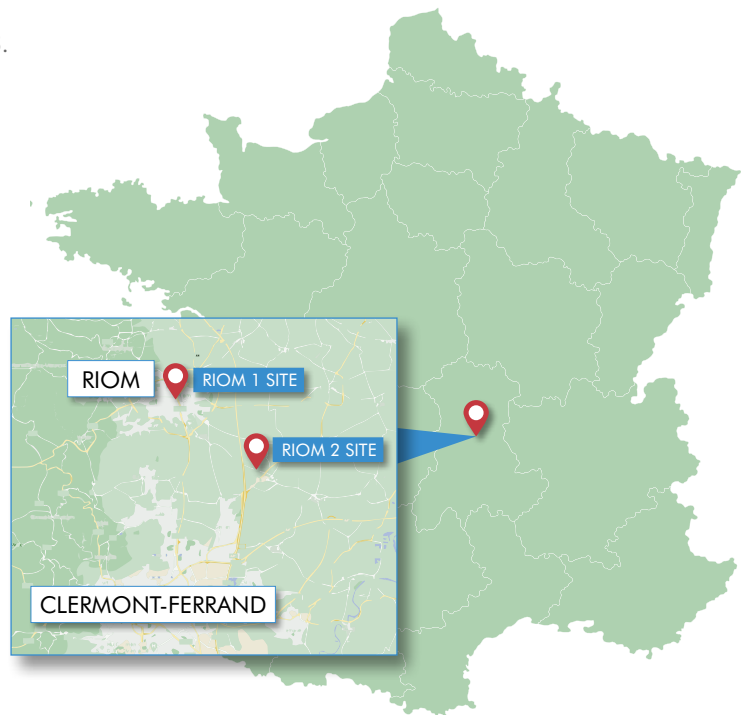
The new state-of-the-art facility in France will offer:

- Larger capacities to supply customers with clinical batches for phase III clinical trials and small-scale for commercial
- Flexibility both in terms of forms (liquid and lyophilised) and in terms of packaging (vials and Prefilled Syringes or Cartridges).
- Ability to handle complex formulations, including a large range of APIs from biologics to highly potent compounds.
- This new site will be situated a few kilometres away from the original Riom site, in the city of Saint Beauzire - North of Clermont-Ferrand in Auvergne, France.
- Operations will commence during Q1 of 2023.

•• FACILITY CAPABILITIES

The all-inclusive facility will contain:




- 2 R&D Laboratories
- 2 Quality Control Laboratories: microbiology, physico & bio-chemistry
- 2 Manufacturing areas including formulation and aseptic filling
 - Line 1: Liquid and lyophilised form - Vials
 - Line 2: Fill&Finish - Vials, Prefilled Syringes and Cartridges
- Supports Services: Logistics, Utilities, Maintenance, Project management and administrative area



This project was supported by the government as part of the Recovery Plan so called "France Relance".



•• PRODUCTION LINE

	LINE 1 - LIQUID & LYOPHILISED	LINE 2 - VIALS, PFS & CARTRIDGES
FORMULATION	Up to 400 Litres tank	
ISOLATOR		
FILLING LINE		
LYOPHILISER		
BATCH SIZE	30k units of 2R – up to 45k	3.6k units per hour
FORMATS	Vials from 2 to 100ml	Vials from 2 to 100ml PFS 1 to 10ml (option) Cartridges (option)
API CATEGORIES	Full containment - From Cat 1 to Cat 4+	
SPECIAL FEATURES	Low temperature - Inert atmosphere - Viscous products - Aseptic formulation - Minimised losses	

•• DEVELOPMENT AND ANALYTICAL CAPABILITIES

Process Research & Development platform

- 2 Laboratories including: Isolator, Glovebox, Safety Cabinets
- 2 Lyophilisers, filling and capping machines for PR&D
- Analytical platform including HPLC and uPLC
- Storage chambers with different conditions for stress studies

Quality Control platform

- 2 Laboratories including: Fumehoods and Safety Cabinets
- HPLCs, uPLCs, LC-MS, Ion Chromatography
- Microbiological platform to perform Bioburden, Sterility and endotoxins tests
- Stability chambers for ICH stability studies

•• SITE CONSTRUCTION TIMELINE

